

REMARKS

The present application relates to inbred maize plant and seed PH5DR. Claims 1-10 are pending in the present application. Claim 2 has been amended. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

Information Disclosure Statement

Applicant acknowledges the Information Disclosure Statement (IDS) filed January 29, 2004 has been considered and signed by the Examiner.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2 and 3 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states the "claims are indefinite because claim 2 recites 'the F1 hybrid maize seed of claim 1', which lacks proper antecedent basis in claim 1". The Examiner further states "claim 3 is indefinite because it is dependent on claim 2".

Although not acceding to the Examiner's rejection, in an effort to expedite prosecution Applicant has now amended claim 2, thus alleviating the rejection to claims 2 and 3.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written description regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states "Applicant does not describe the genus of progeny produced by crossing the inbred maize line PH5DR with other maize plants". (Office Action, p. 3).

Applicant respectfully traverses this rejection. Applicant submits that the genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH5DR, which provide an identifying structural feature possessed by all members of the claimed genus. (See U.S. Patent No. 6,727,413; Table A, column 11, lines 57-67 through column 13, lines 1-41).

Exhibit 1, submitted herewith, is a visual representation of the fact that most of the cells in a corn inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes the ten chromosomes are represented by three rectangles in the Exhibits).

When the inbred is used to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells will receive one of the inbred's sets of chromosomes.

As known to one of ordinary skill in the art and as shown in Exhibits 2 and 3, attached herewith, when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. Therefore, the genus of F1 hybrid seed and plants encompassed by Applicant's claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH5DR. Stated in patent terms, it can be said that an F1 hybrid made with PH5DR *comprises* the unique chromosomes of inbred PH5DR. This unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art. For example, SSR markers publicly known at the time of filing this application can be used for this purpose. Applicant further points out that the unique set of chromosomes of PH5DR that will be retained in a hybrid made with PH5DR are described in the SSR profile in the specification and in the copending parent application U.S. Patent No. 6,727,413 (Table A, column 11, lines 57-67 through column 13, lines 1-41).

This set of chromosomes described and disclosed in the parent application, U.S. Patent No. 6,727,413, Table A, is present within the seed of inbred line PH5DR deposited by Applicant at the ATCC. Further, this unique set of chromosomes can be characterized by molecular marker methods and specifically the SSR profile. (See U.S. Patent No. 6,727,413; Table A, column 11, lines 57-67 through column 13, lines 1-41). Therefore, while the Examiner has stated Applicant has not provided guidance, Applicant has provided guidance as to identifying characteristics of the genetic composition of the entire genus of hybrids claimed.

According to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." The unique set of chromosomes of inbred maize line PH5DR is an identifying structural characteristic present in Applicant's seed deposit of PH5DR. The SSR profile of PH5DR is obtainable from the deposit by one of ordinary skill in the art, as evidenced by Table A of the published parent application, U.S. Patent No. 6,727,413.

The Examiner states that Kevern, U.S. Patent No. 5,850,009 suggests "[t]he genetic variation among individual progeny of a *breeding cross* allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather result of manifested genetic variation combined with selection methods, environments and the actions of the breeder." (See Kevern, column 4, lines 41-46, emphasis added). (Office Action, p. 3).

Applicant respectfully traverses. The Examiner refers to a section of Kevern (column 4, lines 41-46) that is specifically discussing segregating populations of seed. A segregating population is not the invention claimed in claims 1-10. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Rather, the F1 hybrids of the present application are based on stable inbred lines where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH5DR, as may be further exemplified by the SSR profile. Kevern states:

"Maize is an important and valuable field crop. Thus a continuing goal of plant breeders is to develop high-yielding maize hybrids that are agronomically sound based on stable inbred lines. The reasons for this goal are obvious: to maximize the amount of grain produced with the inputs used and minimize susceptibility of the crop to pests and environmental stresses. To accomplish this goal, the maize breeder must select and develop superior inbred parental lines for producing hybrids" (column 4, lines 23-31).

Applicant asserts that in order to accomplish the goal of developing maize hybrids it is necessary to identify genetically unique and stable inbred lines, such as the claimed invention, in order to produce the F1 hybrid seed. It is vital to conceptually understand that the cited section of Kevern by the Examiner is not describing the use of stable inbred lines to produce F1 hybrid seed. An

F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics will be present in both the inbred and the F1 hybrid. In contrast, Kevern is describing the development of a genetically segregating population which is distinct from genetically stable F1 hybrid seed. Therefore, Applicant respectfully states the Examiner has misinterpreted the claimed invention and inappropriately applied Kevern to the present invention. The use of stable inbred lines, such as PH5DR, does allow for one of ordinary skill in the art to make F1 hybrids produced from inbred line PH5DR.

Applicant has also provided data (*see* Tables 3, specification p. 44, and Tables 4A-4C, specification p. 45-50) that demonstrate the results of hybrid combinations of PH5DR.

Applicant has provided actual descriptions of F1 hybrids produced with PH5DR in the application as filed. Applicant performed evaluations on the hybrid progenies of PH5DR and provided the results of such evaluation in Tables 3 and 4. The results of these evaluations show that PH5DR is useful in many different F1 hybrid combinations.

For example, see Table 3, titled "Average Inbred by Tester Performance Comparing PH5DR to PH3DT, Crossed to the Same Inbred Testers and Grown in the Same Experiments" on page 44 of the specification. As the title explains, inbred lines PH5DR and PH3DT, were crossed to a large number of common inbreds (ones that were not PH5DR and PH3DT, respectively) and the results of these crosses were evaluated and reported in this table.

Table 3 demonstrates that PH5DR, at the time that the application was filed, had been crossed to different inbred lines in order to produce different F1 hybrid varieties. The tables also show the average scores of those different F1 hybrid varieties for the 18 different traits listed. This data demonstrates that inbred PH5DR performs well in a variety of F1 hybrid crosses, a characteristic referred to by corn breeders as good general combining ability.

In addition, Table 3 shows similar results for PH3DT, a line that is not the subject of this application. The data was provided for PH3DT because such data may be used by a breeder to compare the general combining ability of PH5DR with the general combining ability of PH3DT. This combining ability data can be viewed as a trait of the inbred, and is useful data when comparing two inbred lines. These tables clearly demonstrate the ability of PH5DR to perform well in a broad genus of F1 hybrids.

In addition to the general combining ability of PH5DR as described in Table 3, Applicant has also provided data in Tables 4A-4C that compare a specific F1 hybrid produced from the

cross of inbred PH5DR and inbred PH6KW with other F1 hybrids. (Specification, p. 45-50). This data demonstrates the good specific combining ability of inbred PH5DR. As evidenced by the data, PH5DR can be used to produce an F1 hybrid that exhibits the characteristics of high grain yield, above average test weight, and good overall disease resistance. (See specification, p. 16, lines 25-27). This represents an actual reduction to practice of the claimed invention.

According to the MPEP, § 2163(II)(A)(3)(a)(ii), the written description requirement for a genus may be satisfied by sufficiently describing a representative number of species actually reduced to practice. Applicant has provided data in Table 3 for F1 hybrid combinations made with PH5DR whose F1 hybrid seed and plants were reduced to practice as of the filing date. Accordingly, the Applicant has satisfied the written description requirement for claims 1-10.

As stated above, the essential test of written description is whether Applicant has demonstrated possession of a claimed invention such that one skilled in the relevant art would recognize that the Applicant was the inventor of the invention as claimed. Applicant has taught that the main utility of an inbred line is to produce F1 hybrid seed and plants. (See specification, p.15, lines 16-17). As the Examiner has acknowledged, Applicant has provided guidance for the traits exhibited by crossing the inbred parent PH5DR with another inbred parent thereby producing an actual F1 hybrid seed and plant. Applicant has made a deposit of inbred PH5DR that fully enables others to make the genus of F1 hybrid seed and plants of claims 1-10. One skilled in the art would thus recognize that Applicant was in possession of F1 hybrid seed and plants produced from line PH5DR as of the filing date of the application.

B. Enablement regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states the "Applicant does not teach how to make and use the genus of progeny produced by crossing inbred maize line PH5DR with other maize plants ... hence it is unclear how one of skill in the art could reasonably predict how to make and use the claimed maize plants produced from Applicant's exemplified inbred maize plant ". The Examiner goes

on to state the "Applicant only teaches a single double hybrid maize plant having inbred maize line PH5DR as one of its parents". (Office Action, p. 5-6).

The Examiner further states that Kevern, U.S. Patent No. 5,850,009 suggests "[t]he genetic variation among individual progeny of a *breeding cross* allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather result of manifested genetic variation combined with selection methods, environments and the actions of the breeder." (See Kevern, column 4, lines 41-46, emphasis added). (Office Action, p. 5).

Applicant respectfully traverses. As discussed *supra*, the Examiner refers to a section of Kevern (column 4, lines 41-46) that is specifically discussing segregating populations of seed. A segregating population is not the invention claimed in claims 1-10. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Rather, the F1 hybrids of the present application are based on stable inbred lines where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH5DR, as may be further exemplified by the SSR profile. (See U.S. Patent No. 6,727,413; Table A, column 11, lines 57-67 through column 13, lines 1-41). Applicant asserts that in order to accomplish the goal of developing maize hybrids it is necessary to identify genetically unique and stable inbred lines, such as the claimed invention, in order to produce the F1 hybrid seed. It is vital to conceptually understand that the cited section of Kevern by the Examiner is not describing the use of stable inbred lines to produce F1 hybrid seed. An F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics will be present in both the inbred and the F1 hybrid. In contrast, Kevern is describing the development of a genetically segregating population which is distinct from genetically stable F1 hybrid seed. Therefore, Applicant respectfully reiterates that the Examiner has misinterpreted the claimed invention and inappropriately applied Kevern to the present invention. The use of stable inbred lines, such as PH5DR, does allow for one of ordinary skill in the art to make F1 hybrids produced from inbred line PH5DR.

The Examiner also cites Carbone, U.S. Patent No. 5,763,755 stating that "[e]ven if an inbred in hybrid combination has excellent yield, *it* may not be useful because *it* fails to have acceptable parental traits such as yield, seed size, pollen production, good silks, plant height, etc". (Office Action, p. 5, emphasis added).

Applicant traverses this argument. The Examiner cites Carlonc which states:

"Maize breeders select for a variety of traits in inbreds that impact hybrid performance along with selecting for acceptable parental traits. Such traits included yield potential in hybrid combination; dry down; grain moisture at harvest; greensnap; resistance to root lodging; resistance to stalk lodging; grain quality; disease and insect resistance; ear and plant height; performance in different soil types such as: low level of organic matter, clay, sand, black, high pH, low pH; performance in: wet environments, drought environments, and no tillage conditions. These traits appear to be governed by a complex genetic system that makes selection and breeding of an inbred line extremely difficult. Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it [the inbred] may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlonc, paragraph bridging columns 1 and 2, language in [] added by Applicant for clarification).

Carlonc is discussing the traits of the inbred (or parental) line and their development. The referenced section of Carlonc is specifically discussing selection within the segregating populations of seed that a breeder uses for inbred development. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Further, the patent cited by the Examiner is one in which Carlonc developed a novel inbred line and sought and was allowed claims to the hybrid seed and plants produced from the novel inbred line. Therefore, Applicant respectfully states the Examiner has misinterpreted the cited portion of the Carlonc reference and has inappropriately applied Carlonc to the present invention. The use of stable inbred lines, such as PH5DR, does enable one of ordinary skill in the art to create hybrids comprising the chromosomes of PH5DR.

The Examiner goes on to cite Segebart, U.S. Patent No. 5,304,719 stating that "[b]ased on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F2 or S0 populations and that typically the genotype of neither the parents nor the desired genotype is known in detail". (Office Action, p. 5-6).

Applicant traverses this argument. As discussed *supra* with respect to Kevern, Applicant asserts that Segebart is discussing segregating F2 populations of seed. In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. The claimed F1 hybrids are not from a segregating population but rather from a highly

homogeneous, homozygous and reproducible inbred maize line PH5DR. (Specification, p. 15, lines 17-18). An F1 hybrid is not the result of a segregating population as cited by the Examiner but rather is the result of a superior, stable and genetically fixed inbred maize line that produces the claimed F1 hybrids. Thus, Applicant respectfully states the arguments set forth by the Examiner do not apply to the presently claimed invention.

The Examiner goes on to cite Segebart, U.S. Patent No. 5,367,109 stating that "[t]he number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that the inbred lines which are used as parents for *breeding crosses* differ in the number of combination of these genes." (Office Action, p. 6, emphasis added).

Applicant traverses this argument. As discussed *supra* with respect to Kevern and Segebart '719, Applicant asserts that Segebart '109 is discussing segregating F2 populations of seed. In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. The claimed F1 hybrids are not from a segregating population but rather from a highly homogeneous, homozygous and reproducible inbred maize line PH5DR. (Specification, p. 15, lines 17-18). Thus, Applicant respectfully states the arguments set forth by the Examiner do not apply to the presently claimed invention.

It is important to note that inbred maize lines are primarily used to produce F1 hybrid seed and plants. The claimed F1 hybrid seed is routinely and easily produced by crossing a plant from an inbred maize line PH5DR with a plant from another inbred maize line.

Applicant has made a deposit of inbred PH5DR that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids. Accordingly, Applicant submits that claims 1-10 are fully enabled. The SSR profile of PH5DR is obtainable from the deposit by one of ordinary skill in the art, as evidenced by the published parent application, U.S. Patent No. 6,727,413 (see Table A, column 11, lines 57-67 through column 13, lines 1-41).

It is important to note that one of ordinary skill in the art would know that the pericarp tissue of inbred PH5DR is genetically identical to the maternal parent. It is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. The pericarp tissue that surrounds the seed is 2n maternal tissue only, the embryo is 2n tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is 3n tissue resulting from the fusion of two maternal and one paternal gametes. The

seed of maize has been described as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel. Therefore, Applicant points out that intact cells from inbred PH5DR will be a component of the F1 hybrid seed produced with PH5DR as the maternal parent. Further, the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH5DR and can be characterized by molecular markers.

Accordingly, Applicant submits that claims 1-10 are fully enabled. In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Double Patenting

Statutory Type Double Patenting

The Examiner rejects claims 5-6 under the statutory type double patenting under 35 U.S.C. § 101 as being unpatentable over claims 2 and 3 of the present application. The Examiner states "claims 5 and 6 will be objected to under 37 C.F.R. § 1.75 as being a substantial duplicate thereof". (Office Action, p. 6-7).

Applicant respectfully traverses this rejection. Claims 2 and 3 are not a substantial duplicate of claims 5 and 6 when read upon the claims from which they depend. Claims 2 and 3 claim a maize plant with "at least one set of the chromosomes of maize inbred line PH5DR". In contrast, claims 5 and 6 are limited to the F1 hybrid maize seed only. Further, although not acceding to the Examiner's rejection, in an effort to expedite prosecution Applicant has now amended claim 2, thus alleviating the rejection. Therefore, Applicant submits that the claims are in proper form for allowance and respectfully request reconsideration and withdrawal of the provisional statutory type double patenting rejection under 35 U.S.C. § 101.

Obviousness-Type Double Patenting

The Examiner rejects claims 1-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending U.S. Patent No. 6,727,413. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the method of making an F1 hybrid maize plant

from inbred maize line PH5DR of the '413 patent renders obvious the claimed hybrid maize plant of the instant claims.

Applicant is herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c), which disclaims any term of a patent issuing from this application which would extend beyond the term of copending U.S. Patent No. 6,727,413. Therefore, Applicant submits that the claims are in proper form for allowance and respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

Summary

35 U.S.C. § 112, second paragraph

Applicant respectfully asserts these rejections have been alleviated by amendment to the claims.

35 U.S.C. § 112, first paragraph - Written Description and Enablement regarding Claims 1-10

Applicant submits there has been adequate written description and a reduction to practice of the claimed F1 hybrid genus. The genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH5DR, which provide an identifying structural feature possessed by all members of the claimed genus. Specifically, the genus of F1 hybrid seed and plants encompassed by Applicant's claims all share the common structural attribute of having a complete set of the chromosomes of PH5DR, and a description of the set of chromosomes is disclosed in Table A of the published parent application, U.S. Patent No. 6,727,413. In addition, the SSR profile of PH5DR is obtainable from the deposit of PH5DR by one of ordinary skill in the art, utilizing SSR markers publicly known at the time of filing this application. In addition, the F1 hybrid seed also will comprise an intact cell from inbred maize line PH5DR when PH5DR is the maternal parent. Therefore, one of ordinary skill in the art would thus recognize that Applicant was in possession of F1 hybrid maize seed and plants produced from PH5DR. Applicant respectfully submits that claims 1-10 are adequately described.

Applicant also respectfully asserts that the claimed invention is enabled by the present application. The claimed F1 hybrid seed is produced by crossing a plant from inbred maize line PH5DR with a plant from another inbred maize line whereby the F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it. Seed of inbred line PH5DR has been

deposited and it is well known to one skilled in the art how to use PH5DR to produce F1 hybrid seed. Applicant has created a novel maize inbred line PH5DR, and by virtue of the deposit of PH5DR, one of ordinary skill in the art is fully enabled to produce inbred maize line PH5DR and F1 hybrid seed and plants produced from PH5DR.

It is respectfully submitted that Applicant has described and enabled the production of the F1 hybrid seed and plants produced with PH5DR, and are entitled to the scope of their invention as claimed.

Double Patenting

Statutory Type Double Patenting

Applicant has now amended claim 2. Therefore, Applicant requests reconsideration and withdrawal of the statutory type double patenting rejection under 35 U.S.C. § 101.

Obviousness-Type Double Patenting

Applicant is herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c). Therefore, Applicant submits that the claims are in proper form for allowance and requests withdrawal of the obviousness-type double patenting rejection.

Applicant further acknowledges that the claims (1-10) are deemed free of the prior art. The Examiner further states the prior art fails to teach or suggest F1 progeny of inbred maize line PH5DR.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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